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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,772	04/18/2005	Kenji Tanaka	234732	5210

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LEYDIG VOIT & MAYER, LTD  
TWO PRUDENTIAL PLAZA, SUITE 4900  
180 NORTH STETSON AVENUE  
CHICAGO, IL 60601-6731

EXAMINER
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STEELE, AMBER D

ART UNIT	PAPER NUMBER
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1639

MAIL DATE	DELIVERY MODE
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11/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/527,772	TANAKA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007 and 04 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 6, 7, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/11/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. Please note: the examiner of record for the present application has changed. The Technology Center (TC1600) and Art Unit (AU1639) remain the same.

#### ***Status of the Claims***

2. The amendment received on November 9, 2007 amended claims 1 and 8, canceled claim 5, and added new claims 12-13.

Claims 1-4 and 6-13 are currently pending.

Claims 8-11 are currently under consideration.

#### ***Election/Restrictions***

3. Applicant's election with traverse of Group II (claims 8-11) in the reply filed on November 9, 2007 is acknowledged. The traversal is on the ground(s) that Tanaka et al. does not teach a library of membrane protein-embedded liposomes with a weight ratio of the membrane proteins to lipids constituting the liposomes from 0.01 to 0.8. This is not found persuasive because the "special technical feature" of a weight ratio of the membrane proteins to lipids constituting the liposomes from 0.01 to 0.8 was not present in the claims at the time the Lack of Unity was made. In addition, Munechika et al. (U.S. Patent 5,662,931 issued September 2, 1997) teach a weight ratio of the membrane proteins to lipids constituting the liposomes of 0.1 to 0.5 (see the entire specification particularly column 3, lines 22-24).

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 1-4, 6-7, and 12-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

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claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 9, 2007.

5. Upon further consideration, the species requirement is withdrawn.

***Priority***

6. The present application claims status as a National Stage application (i.e. 371) of PCT/JP04/10540 which is a CIP of 10/622,002 filed July 17, 2003.

7. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/622,002, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. U.S. application 10/622,002 does not provide support for a weight ratio of membrane proteins to lipids from 0.01 to 0.8 (i.e. 0.05 or less was found) or a lower limit of  $10^5$  regarding library members (i.e.  $10^6$  is lowest limit). Therefore, the presently claimed invention has a priority date of the filing date of PCT/JP04/10540 (filed July 16, 2004).

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***Information Disclosure Statement***

8. The information disclosure statement (IDS) submitted on March 11, 2005 is being considered by the examiner.

***Specification***

9. The use of the trademarks including Polytron® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Sequence Compliance***

11. The present application does not contain any nucleic acid or amino acid sequences. Therefore, the present application does not require a sequence listing or CRF.

***Claim Objections***

12. Claims 8-11 are objected to because of the following informalities: claim 8 depends on withdrawn claim 1. Appropriate correction is required. Applicants may wish to incorporate structural limitations of present claim 1 into present claim 8.

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***Invention as Claimed***

13. A library of membrane protein-embedded liposomes...which comprises about  $1 \times 10^5$  or more membrane protein-embedded liposomes wherein the liposomes have a diameter of 10 nm or more and wherein the amount of membrane proteins is about 10 fg or more and variations thereof.

14. The presently claimed product incorporates the method of claim 1 via dependency, therefore, the present claims are considered product-by-process claims. See MPEP § 2113. The only structural limitation within claim 1 is that the weight ratio of the membrane proteins to lipids constituting the liposomes is from 0.01 to 0.8 which has been considered in the search of the prior art.

***Claim Rejections - 35 USC § 112***

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. Claims 8-10 require the amount of proteins to be about 10 fg, 1pg, or 10 pg. However, it is not clear from the claims if the amount of protein is per liposome or if the amount of protein is per library.

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***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. U.S. Patent 6,056,973 issued May 2, 2000 and Tanaka et al. WO 02/056026 published July 18, 2002 (effective filing date of January 9, 2001).

For present claims 8-11, Allen et al. claim a library of liposomes (e.g. library = more than one; open-ended range encompassing  $10^5$ ,  $10^8$ ) comprising proteins including antibodies, Fab, ICAM-1, VCAM-1, etc. wherein the liposomes are 100 nm in diameter, between 1-20 mole percent of lipid is present in the liposome formation, 1.2 mole percent of protein, and 12, 20, 33, 40, and 70 proteins can be in each liposome wherein the proteins can have molecular weights of 3,000 Da (Fab), 90-110 kDa (ICAM-1), etc. (please refer to the entire specification particularly columns 2-8).

However, Allen et al. does not specifically teach 10 fg, 1 pg, 10 pg, or more protein.

For present claims 8-11, Tanaka et al. teach protein embedded liposomes comprising ng amounts of protein (please refer to the entire specification particularly Figure 19; Examples 1-5).

The claims would have been obvious because the substitution of one known element (i.e. liposome with less than 10 fg, 1 pg, or 10 pg protein as taught by Allen et al.) for another (i.e. liposome with ng amount of protein taught by Tanaka et al.) would have yielded predictable results (i.e. more protein in liposome) to one of ordinary skill in the art at the time of the

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invention. In addition, if “a person of ordinary skill has good reason to pursue the known options within his or her technical grasp” (e.g. size of library, size of liposome, etc.), then “it is likely the product is not of innovation but of ordinary skill and common sense”. Furthermore, it is noted that various limitations including the size of the library, the size of the liposome, the weight ratio, and the amount of protein are normal experimental design choices and/or optimization for a desired outcome and routine in the art. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

19. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perrott et al. U.S. Patent 6,217,901 issued April 17, 2001; Tanaka et al. WO 02/056026 published July 18, 2002 (effective filing date of January 9, 2001); and Munechika et al. U.S. Patent 5,662,931 issued September 2, 1997.

For present claims 8-11, Perrott et al. teach synthetic polymer complements (SPCs; liposomes; plurality = library, open-ended range of two or more encompassing  $10^5$ ,  $10^8$ ) that range in size from about 20 to about 1000 nm and containing 1 to about 10,000 template molecules which can be membrane proteins (please refer to the entire specification particularly the abstract; Figures 1A-1C; columns 2-4, 9-11).

However, Perrott et al. does not teach 10 fg, 1 pg, or 10 pg of protein.

For present claims 8-11, Tanaka et al. teach protein embedded liposomes comprising ng amounts of protein (please refer to the entire specification particularly Figure 19; Examples 1-5).

However, Perrott et al. does not teach weight ratio of proteins to lipids of 0.01 to 0.8.



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For present claims 8-11, Munechika et al. teaches liposomes containing physiologically active proteins at a protein to lipid ratio of 0.1 to 0.5 (please refer to the entire specification particularly column 3, lines 22-24; see also the abstract; columns 2-3).

The claims would have been obvious because the substitution of one known element (i.e. liposome with less than 10 fg, 1 pg, or 10 pg protein as taught by Perrott et al.; liposome with unknown weight ratio as taught by Perrot et al.) for another (i.e. liposome with ng amount of protein taught by Tanaka et al.; weight ratio of 0.1 to 0.5 taught by Munechika et al.) would have yielded predictable results (i.e. more protein in liposome; specific protein to lipid ratio) to one of ordinary skill in the art at the time of the invention. In addition, if “a person of ordinary skill has good reason to pursue the known options within his or her technical grasp” (e.g. size of library, size of liposome, etc.), then “it is likely the product is not of innovation but of ordinary skill and common sense”. Furthermore, it is noted that various limitations including the size of the library, the size of the liposome, the weight ratio, and the amount of protein are normal experimental design choices and/or optimization for a desired outcome and routine in the art. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

#### ***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/  
Patent Examiner, Art Unit 1639

November 13, 2008